

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

WILLIAM A. JACOBSON, on behalf of himself and
others similarly situated,

Plaintiff,

22-CV-0033

-against-

MAD/ML

MARY T. BASSETT, in her official capacity as Acting
Commissioner of the New York Department of Health,

Defendant.

**MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR A
PRELIMINARY INJUNCTION AND IN SUPPORT OF DEFENDANT'S CROSS-
MOTION TO DISMISS THE COMPLAINT**

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Defendant, Mary T. Bassett, Commissioner of the New York State Department of Health, sued in her official capacity (“Defendant”), submits this memorandum of law, together with the accompanying Declaration of Eugene Heslin, MD, FFAFP, dated February 17, 2022, (“Heslin Decl.”), and its exhibits, (1) in opposition to Plaintiffs’ motion for a preliminary injunction enjoining the enforcement of a Department of Health (“DOH”) guidance document that advises health care providers that a patient’s non-white race or Hispanic/Latino ethnicity may be deemed a risk factor that increases the patient’s risk for severe illness associated with COVID-19; and (2) in support of Defendant’s motion to dismiss the Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

PRELIMINARY STATEMENT

The State of New York, along with the rest of the world, continues to confront the greatest public health crisis in a century. The enormous number of deaths in New York State caused by the COVID-19 pandemic could have been far higher had the State not taken urgent action to halt the spread of the virus. Thanks to these measures, New York “flattened the curve” for new infections and fatalities. But the danger is certainly not over. Positivity rates in the state have continued despite widespread availability of vaccination.¹ Concerns about increases in hospitalization rates resulting from COVID-19 have prompted the Governor of the State to declare a new state of emergency now extended through March 16, 2022.² Most recently, the World Health Organization’s classification of the new Omicron variant as a “variant of concern” has, once again,

¹ See <https://coronavirus.health.ny.gov/positive-tests-over-time-region-and-county> (last accessed on Feb. 17, 2022).

² See Executive Order 11.3, <https://www.governor.ny.gov/executive-order/no-113-declaring-disaster-emergency-state-new-york> (last accessed on Feb. 16, 2022).

added to the concerns of public health experts about the spread of COVID-19.³ As such, the State continues to carefully calibrate its response to ensure that the health and lives of New Yorkers remain protected from the virus.

To advance these efforts, on December 27, 2021, DOH issued a guidance document to New York State health care providers and health care facilities entitled “COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products” (“Guidance”), which advises about available COVID-19 outpatient therapeutics, including newly authorized oral antiviral treatments, and lists the eligibility criteria for their use. Guidance, Heslin Decl., Exh. A, p. 1-2. One of the various criteria requires that a patient “have a medical condition or other factors that increase their risk for severe illness,” and that “[n]on-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19.” *Id.*, p. 2.

Plaintiff is a white law professor who does not have COVID-19 and seeks to represent a class of all white people. Complaint, ECF No. 1 (“Compl.”). Plaintiff seeks an order (1) certifying a class of “individuals in New York State who do not qualify under the New York health department guidelines for distribution of COVID-19 therapeutics as ‘[n]on-white race or Hispanic/Latino ethnicity;’” (2) declaring that the racial consideration contained in the Guidance violates the Fourteenth Amendment, Title VI and the Affordable Care Act (“ACA”); and (3) enjoining the enforcement of the racial consideration contained in the Guidance.⁴ Compl., ¶ 32.

³ See <https://www.cdc.gov/media/releases/2021/s1126-B11-529-omicron.html> (last accessed on Feb. 17, 2022).

⁴ A similar challenge to the Guidance is currently pending in the Eastern District of New York before Judge Nicholas Garaufis in the case of *Roberts v. Bassett*, CV 22-710.

Plaintiff fails to demonstrate a likelihood of success, irreparable harm or that the balance of the equities and public interest favor issuance of the preliminary injunction. Additionally, the Complaint fails to state legally cognizable claims because (1) Plaintiff lacks standing; (2) Plaintiff's claims are moot because there is no shortage of antiviral therapies; (3) Plaintiff is not entitled to injunctive relief because Defendant is not, and will not engage in enforcement activities related to the Guidance; (4) the Guidance is narrowly tailored to serve the state's compelling interest in ensuring that scarce COVID-19 antiviral therapies are given to those patients most likely to suffer severe illness; and (5) Plaintiff's allegations are insufficient to state claims under Title VI or the Affordable Care Act ("ACA"). Accordingly, Plaintiffs' motion must be denied in its entirety, and Defendant's cross-motion should be granted.

STATEMENT OF FACTS

A. The COVID-19 Pandemic and New York's Response

The lives of individuals around the world, including New York State, have been impacted by COVID-19 and measures enacted to prevent its spread. Heslin Decl., ¶ 6. Since the onset of the pandemic, DOH has vigorously applied all resources and taken all measures legally at its disposal to ensure the safety and welfare of all New Yorkers, including closely aligning state efforts with guidance and requirements released by the Centers of Disease Control and Prevention ("CDC"). *Id.* The outbreak of the new Omicron variant, in early December was handled no differently. *Id.*, ¶ 7. The full weight of resources available to DOH were immediately brought to bear on the issue. *Id.* Testing capacity was ramped up to meet demand, engagement on vaccination and boosting efforts intensified, and the mandatory masking protocols in public spaces were extended. *Id.* DOH efforts have been successful in leading to a 90 percent drop in the state's positivity rate in the last month. *Id.*, ¶ 8.

B. Drug Treatments/Therapies and Issuance of the Guidance

In December of 2021, as the Omicron variant began to surge, the Food and Drug Administration (“FDA”) issued Emergency Use Authorizations for a number of drug treatments and therapies that were found to reduce the risk of hospitalization and death in high-risk patients when taken by the patients early after symptom onset. *Id.*, ¶ 10. These include Paxlovid and Molnupiravir two antiviral therapies and Sotrovimab a monoclonal antibody product (collectively referred to as “antiviral therapies”). *Id.* Shortly after their release, supply shortages of these drug treatments and therapies began to present.⁵ *Id.* As a result, DOH released the December 27, 2021, Guidance to make providers and hospitals aware of the newly authorized treatments. *Id.* It was issued by DOH to health care providers and health care facilities to advise them of, among other things, the treatment and prevention of severe COVID-19 with oral antivirals within certain categories, including those with risk factors for severe illness. *Id.*, ¶ 9.

Broadly, the Guidance (1) summarizes the antiviral treatment modalities; (2) reviews the recommended parameters for use and eligibility for antiviral treatments; (3) discusses the clinical considerations for antiviral treatments; (4) reviews the process for referring patients for antiviral treatment within and outside New York City to ensure equitable access; and (5) reviews changes in the use of monoclonal antibodies. *Id.*, ¶ 12. The language at issue in this litigation falls within the eligibility section of the Guidance, which was meant to advise about health-based risk factors to consider when providing treatment. *Id.*, ¶ 13.

Plaintiff takes issue with the portion of the Guidance advising providers and hospitals that they should consider race and ethnicity as a risk factor when making decisions as to whether

⁵ Importantly, while the Guidance was issued at a time when antiviral therapies were anticipated to be in short supply, there is not currently a shortage of treatments. Heslin Decl., ¶ 27.

an individual meets the criteria for oral antiviral treatment: “Non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19.” *Id.*, ¶ 13. This language tracks CDC guidance published in the “Federal Response to COVID-19 Therapeutics Clinical Implementation Guide,” which states that antibody therapies may be authorized for individual patients at high risk for severe illness from COVID-19 because of certain medical or other factors, including race or ethnicity. *Id.*, ¶ 15.

C. The Scientific Basis for the Guidance

Consideration of race and ethnicity as a risk factor for increased severe illness and death from COVID-19 is supported by objective data. For instance, an analysis of treatment data by the CDC showed that antiviral therapies are used less commonly among racial and ethnic minority groups, thus amplifying the increased risk for severe COVID-19-associated outcomes in those groups. *Id.*, ¶ 16. Additionally, a National Center for Health Statistics 2020 Report demonstrated a disproportionate impact on life expectancy of Hispanic and black people due to the COVID-19 pandemic. *Id.*, ¶ 17.

Further, a study published on December 10, 2020, found that people from racial and ethnic minority groups were more likely to have increased COVID-19 disease severity upon admission to the hospital when compared with non-Hispanic white people. *Id.*, ¶ 18. Mortality data from CDC’s National Vital Statistics System (“NVSS”), from February 1, 2020, to September 30, 2021, demonstrates that there have been an estimated 700,000 deaths in the United States, with the largest percentage increase in mortality among adults aged 25–44 years and among Hispanic or Latino people. *Id.*

An article in *Scientific Reports* illustrates that racial disparities continue to persist even after controlling for medical comorbidities. *Id.*, ¶ 19. When compared to white patients, similarly situated black patients showed significantly higher odds of ventilator dependence and death. *Id.* Similarly, an article in the *Journal of the American Medical Association Network Open* entitled “Variations in COVID-19 Mortality in the US by Race and Ethnicity” found that most racial and ethnic minority populations had higher age-adjusted mortality rates than non-Hispanic white populations. *Id.*, ¶ 20. Finally, data compiled by the CDC demonstrates that non-white and Hispanic/Latino individuals suffer COVID-19 infection, hospitalization and death at far greater rates than white patients. *Id.*, ¶ 21.

All of this data supports that non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19 in non-white communities. *Id.*, ¶ 22.

D. The Guidance in Operation

The Guidance was issued at a time when oral antiviral treatments were anticipated to be in short supply based upon information provided by the federal government prior to their initial distribution. *Id.*, ¶ 28. However, there is currently no shortage of the medications in New York, *id.*, and no one in New York, who is otherwise qualified based on their individual risk factors, will be turned away from life-saving treatment because of their race or any demographic identifier. *Id.*, ¶ 31. Due to the lack of a shortage, the Guidance has been removed from the DOH website. *See* <https://coronavirus.health.ny.gov/covid-19-guidance-repository>, generally (last visited Feb. 18, 2022).

The recommendation that providers and hospitals should consider race and ethnicity as a risk factor when prescribing oral antiviral treatments is not a mandate, or a restriction of COVID-19 treatments by race. *Id.*, ¶ 24. The Guidance does not replace doctors' clinical judgment and does not prevent any patient from receiving necessary treatment. *Id.* Rather, the Guidance is intended to address the well-documented reality that communities of color have been disproportionately impacted by the COVID-19 pandemic. *Id.* This has been reiterated publicly in discussion about using these medications, including DOH presentations in multiple venues including: (1) a widely publicized and attended New York State and New York City webinar; (2) monthly calls held by the New York State Medical Society and New York State Association of County Health Officials (attended by public health directors of any county that chooses to participate) and (3) weekly regional calls with hospitals, county officials, and advocacy organizations. *Id.*

The Guidance does not, nor is it intended to, operate as a barrier to care for white people or create a racial hierarchy in the delivery of care.⁶ *Id.*, ¶ 25. It is expected that, in a clinical setting, a practitioner should: (1) take a detailed history and conduct a physical examination; (2) understand the risks and benefits of treatment versus non treatment based upon the individual patient; and (3) have a discussion with the patient about risks, benefits, and alternatives. *Id.* Only then, after using appropriate medical clinical judgment, should a medication be prescribed. *Id.* These decisions should always be based upon the physician-patient relationship and a shared

⁶ To provide an example at the extremes, as contemplated by Plaintiff: a white person and person of color both present to a treating doctor; only one oral antiviral treatment is available; the white person has various comorbidities and is in a seriously medically compromised state; the person of color presents as asymptomatic with no comorbidities. In this situation DOH would expect the physician, using her or his medical judgment, to prescribe the one antiviral treatment available to the white person. Heslin Decl., ¶ 25.

decision-making process that is part and parcel to patient care. *Id.* Guidance issued by DOH is simply a suggestion to help focus the thoughts of practitioners and inform reasonable discussion.

Id.

In short, the Guidance is just that—guidance.⁷ *Id.*, ¶ 26. It is not a substitute for the use of sound clinical judgment by practitioners or hospitals. *Id.* It merely points to one of many factors to be considered when prescribing treatment. *Id.* All things being equal among patients, the Guidance is meant to allow the flexibility for health care providers to consider persons of color as being at an increased risk due to the disproportionate impact of COVID-19 on communities of color. *Id.* Nothing in the Guidance prevents the Plaintiff, or anyone similarly situated, from receiving treatment with oral antivirals in the unfortunate event that they contract COVID-19. *Id.*, ¶ 30. No one in New York, who is otherwise qualified based on their individual risk factors, will be turned away from life-saving treatment because of their race or any demographic identifier. *Id.*, ¶ 31.

STANDARDS OF REVIEW

A. Preliminary Injunction

Injunctive relief, such as the preliminary injunction sought by Plaintiff, is “an extraordinary remedy *never* awarded as of right.” *Winter v. NRDC, Inc.*, 555 U.S. 7, 24 (2008) (emphasis added). The movant bears the burden of establishing, by clear and convincing evidence, that (a) he is likely to succeed on the merits; (b) he is likely to suffer irreparable harm in the absence of preliminary relief; (c) the balance of equities tips in his favor; and (d) an injunction is in the public interest. *Winter*, 555 U.S. at 20. The final two factors—the balance of

⁷Because the Guidance is not a mandate, DOH will not take enforcement actions against practitioners or hospitals in relation to it. Heslin Decl., ¶ 27.

equities and the public interest—“merge when the Government is the opposing party.” *L&M Bus Corp. v. Bd. of Educ. of the City Sch. Dist. N.Y.*, 2018 U.S. Dist. LEXIS 88354, at **45-46 (E.D.N.Y. May 25, 2018) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

In addition, the Second Circuit has “held the movant to a heightened standard” where (i) an injunction is “mandatory” (i.e., altering the status quo, rather than maintaining it), or (ii) the injunction “will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits.” *New York v. Actavis PLC*, 787 F. 3d 638, 650 (2d Cir. 2015). In such cases, the movant must show a “clear” or “substantial” likelihood of success on the merits and make a “strong showing” of irreparable harm, in addition to showing that the preliminary injunction is in the public interest. *See id.* (quoting *Beal v. Stern*, 184 F.3d 117, 123 (2d Cir. 1999) and *Doe v. New York University*, 666 F. 2d 761, 773 (2d Cir. 1981)).

B. Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(1)

A complaint should be dismissed under Fed. R. Civ. P. 12(b)(1) “for lack of subject matter jurisdiction if the court ‘lacks the statutory or constitutional power to adjudicate it.’” *Cortlandt St. Recovery Corp. v. Hellas Telecomm.*, 790 F. 3d 411, 416-17 (2d Cir. 2015) (quoting *Makarova v. U.S.*, 201 F. 3d 110, 113 (2d Cir. 2000)). “The party asserting subject matter jurisdiction ‘bears the burden of proving subject matter jurisdiction by a preponderance of the evidence.’” *Martinez v. Malloy*, 350 F. Supp. 3d 74, 83 (D. Conn. 2018) (quoting *Aurecchione v. Schoolman Transp. Sys., Inc.*, 426 F. 3d 635, 638 (2d Cir. 2005)). While the court must accept all material factual allegations contained in the complaint as true, it is “not to draw inferences from the complaint favorable to the plaintiffs.” *J.S. v. Attica Cent. Sch.*, 386 F. 3d 107, 110 (2d Cir. 2004). “At the pleading stage, ‘standing cannot be inferred argumentatively

from averments in the pleadings, but rather must affirmatively appear in the record.”” *Martinez*, 350 F. Supp. 3d at 84 (quoting *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 232 (1990)) (internal quotation marks omitted).

C. Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6)

To survive a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), a complaint “must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This standard places a very real burden on the plaintiff, whose claim cannot go forward if the complaint offers merely “labels and conclusions” or “naked assertions devoid of further factual enhancement.” *Id.* at 677-78. It is only the well-pled facts that the court can accept as true: “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Id.* at 678. Accordingly, the court’s task is to test the legal sufficiency of a complaint, and to dismiss the action “when it is clear from the face of the complaint, and matters of which the court may take judicial notice, that the plaintiff’s claims are barred as a matter of law.” *Parkcentral Global Hub Ltd. v. Porsche Auto. Holdings SE*, 763 F.3d 198, 208-09 (2d Cir. 2014).

ARGUMENT

POINT I

PLAINTIFF FAILS TO SHOW LIKELIHOOD OF SUCCESS ON THE MERITS AND THE COMPLAINT FAILS TO STATE A CLAIM

A. Plaintiff Lacks Standing

Federal courts may only adjudicate “cases and controversies within the scope of Article III of the U.S. Constitution.” *Martinez*, 350 F. Supp. 3d at 84. To establish standing under Article III, a party must show (1) an “injury in fact;” (2) “a causal connection between the injury and the conduct complained of;” and (3) a “‘substantial likelihood’ that the requested relief will

remedy the alleged injury in fact.” *Dixie v. Antonacci*, 2017 U.S. Dist. LEXIS 79449, at *17 (N.D.N.Y. May 24, 2017) (quoting *McConnell v. FEC*, 540 U.S. 93, 225 (2003)) (internal quotation marks omitted). It is Plaintiff’s burden to establish that he has standing. *Martinez*, 350 F. Supp. 3d at 85.

Plaintiff alleges that a person of non-white race or Hispanic/Latino ethnicity may receive antiviral therapies because of their race or ethnicity alone, but a person of white race or non-Hispanic/Latino ethnicity must show a medical condition or risk factor to receive the therapies. Plaintiff’s Memorandum of Law, ECF No. 34-1, (“Pl. Mem. of Law”), pp. 5-6, 9. In other words, Plaintiff alleges that the Guidance erects a “barrier” for one group to access antiviral therapies that another group does not face. Pl. Mem. of Law, pp. 5-6, 9. In this type of equal protection claim, an “injury in fact” occurs “[w]hen the government erects a barrier that makes it more difficult for members of one group to obtain a benefit than it is for members of another group.” *Ne. Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 666 (1993). Therefore, to establish Article III standing, Plaintiff must allege the following: (1) “there exists a reasonable likelihood that the plaintiff is in the disadvantaged group, (2) there exists a government-erected barrier, and (3) the barrier causes members of one group to be treated differently from members of the other group.” *Comer v. Cisneros*, 37 F. 3d 775, 793 (2d Cir. 1994).

“[E]ven if a governmental actor is discriminating on the basis of race, the resulting injury ‘accords a basis for standing only to those persons who are personally denied equal treatment by the challenged discriminatory conduct.’” *U.S. v. Hays*, 515 U.S. 737, 743-744 (1995). Plaintiff alleges that he has standing to bring his claims because the provision of the Guidance that permits the consideration of race in determining a patient’s risk factors is a “barrier” to white

people's access to antiviral therapies. However, these allegations are insufficient to establish standing. First, the Guidance is not a "barrier" to Plaintiff's ability to receive antiviral therapies. To establish standing, Plaintiff must prove that the Guidance makes it "more difficult" for white/non-Hispanic or Latino individuals to obtain antiviral therapies than it is for non-white/Hispanic or Latino individuals. *Dixie*, 2017 U.S. Dist. LEXIS at **18-19 (citing *Comer*, 37 F. 3d at 791). As Dr. Heslin explains, "[n]othing in the Guidance prevents the Plaintiff, or anyone similarly situated, from receiving treatment with oral antivirals in the unfortunate event that they contract COVID-19," Heslin Decl., ¶ 30, and "[n]o one in New York, who is otherwise qualified based on their individual risk factors, will be turned away from life-saving treatment because of their race or any demographic identifier." *Id.*, ¶ 31.

Notwithstanding, Plaintiff appears to allege that the "barrier" created by the Guidance is that he must demonstrate a medical condition or other risk factor that increases his risk for severe illness in order to be eligible for antiviral therapies in short supply. Pl. Mem. of Law, pp. 5-6, 9. In order to be prescribed antiviral therapies, a person must have a "medical condition or other factors that increase their risk for severe illness." Guidance, Heslin Decl., Exh. A. And those conditions or factors are evaluated and determined by a physician using his or her medical judgment to determine if antiviral therapy is an appropriate treatment for a particular patient. Heslin Decl., ¶¶ 24-25. There is no "barrier" to Plaintiff's, or any patient's, access to antiviral therapies created by the Guidance. *MGM Resorts Int'l Global Gaming Dev., LLC v. Malloy*, 2016 U.S. Dist. LEXIS 81635, at *20 (D. Conn. 2016) (discussing how the statute was not a "barrier" to a benefit and distinguishing classes of cases to the contrary) *affirmed* 861 F.3d 40 (2d Cir. 2017).

Second, Plaintiff must show that he intends to or is “able and ready” to “pursue the benefit” to establish standing. *Martinez*, 350 F. Supp. 3d at 85. He cannot do so. The allegations in the Complaint, and the proof submitted by Plaintiff in support of his motion for a preliminary injunction—a ten paragraph declaration—states only that Plaintiff wants to “immediately access oral antiviral treatments to reduce [his] risk of serious illness or death” when he “inevitably contracts COVID-19.” Jacobson Declaration, ECF No. 34-2, ¶ 7. But, because he would need to “demonstrate a ‘medical condition or other factors that increase [his] risk for severe illness,’ *id.*, ¶ 9, he has “heightened concern when [he goes] about his daily activities.” *Id.*, ¶ 10.

This kind of speculative and tenuous situation is not the type in which standing is established simply by showing that a plaintiff is a member of a group that cannot access a benefit because of a government-created barrier. Cases in which standing has been established under this theory challenged policies related to benefits associated with things such as the provision of educational opportunities, *see e.g. Martinez*, 350 F. Supp. 3d 74 (challenge to lack of public school alternatives for poor and minority children), college admissions, *see e.g. Gratz v. Bollinger*, 539 U.S. 244 (2003) (challenge to race considerations in University of Michigan admissions policy) and the awarding of government contracts, *see e.g. Ne. Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656 (1993) (challenge to ordinance giving preference in awarding city contracts to minority-owned businesses). In those cases, the plaintiffs were “ready and able” to access educational opportunities, apply to a college or bid on a contract but for the policies at issue that put plaintiffs at a disadvantage because of their race. *See e.g. Martinez*, 350 F. Supp. 3d at 85-87; *Gratz*, 539 U.S. at 262; *Ne. Fla. Chapter of Associated Gen. Contractors of Am.*, 508 U.S. at 658-659.

For instance, in *Ne. Fla. Chapter of Associated Gen. Contractors of Am.*, the plaintiff was an association of contractors who regularly bid on government contracts and performed construction work on government contracts. 508 U.S. at 658-659. The evidence before the court established that contractor-members of the association would have bid on contracts set aside for minority-owned businesses except that they were excluded from participation in the bidding process because they were not owned by an ethnic minority or female. *Id.* The court held that plaintiff had standing because the contractors demonstrated that they would have competed for the set aside contracts but were prohibited from doing so by the government's intentional set aside of particular contracts for a certain classification of businesses that did not include plaintiffs. *Id.* Since the government's policy prohibited plaintiffs from competing because of their race/gender, plaintiff had standing to challenge the policy. *Id.* at 668-669.

Here, Plaintiff does not have COVID-19 and may never contract it. If he does contract it, his physician may or may not deem Plaintiff's medical condition suitable for antiviral therapy. If his physician does deem Plaintiff's condition to be warranted, based upon a full review of his medical history and a discussion of any possible contraindications, Plaintiff may or may not be eligible for the therapy for reasons unrelated to his race. If he is eligible, there is no shortage of antiviral therapies such that the Guidance would be invoked. If there was a shortage, a physician's medical judgment may or may not result in plaintiff receiving the therapy. There is no automatic qualifier/disqualifier for the antiviral therapy and whether or not Plaintiff will ever be given the therapy will be in accordance with his health care provider's medical judgment.

This kind of alleged “some day” intention” to access a benefit was rejected by the court in *Christa McAuliffe Intermediate Sch. PTO, Inc. v. De Blasio* as sufficient to establish standing. In that case, which was a challenge to the admission policies of New York City specialized high

schools, the court stated that students in first and fourth grade may decide not to apply to the specialized high schools whose admission policies were being challenged. 364 F. Supp. 3d 253, 272 (S.D.N.Y. 2019) *affirmed* 788 Fed. Appx. 85 (2d Cir. 2019). Here, Plaintiff may or may not ever contract COVID and his physician may or may not prescribe antiviral therapy to treat it. This is the same kind of speculative and tenuous fact pattern rejected in *Christa McAuliffe*.

Any alleged connection between Plaintiff's claims and any "injury" that he may someday suffer as a result of the Guidance is entirely too speculative and tenuous for Plaintiff to have standing. Rather than establishing an injury in fact, Plaintiff alleges only a "generalized grievance" that is insufficient to establish standing. *Pietrangelo v. Sununu*, 2021 U.S. Dist. LEXIS 65632, at *25 (D. NH April 5, 2021) (denying standing to white plaintiff who challenged the consideration of race and ethnicity in the state's COVID-19 vaccination prioritization plan).

Accordingly, Plaintiff is not likely to succeed on his claims because he lacks standing, and the Complaint should be dismissed for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1).

B. Plaintiff's Claims are Moot

"Article III of the Constitution limits federal-court jurisdiction to 'cases' and 'controversies.'" *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 160 (2016) (citing U.S. Const., Art. III, § 2). There is no case or controversy when a claim becomes moot. *Chafin v. Chafin*, 568 U.S. 165, 172 (2013). "No matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute 'is no longer embedded in any actual controversy about the plaintiffs' particular legal rights.'" *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013).

Plaintiff's claims are moot. Plaintiff challenges a Guidance issued specifically to address a situation in which there is an antiviral therapy supply shortage. There is no longer a shortage of antiviral therapies. Heslin Decl., ¶¶ 27-28. Any patient for whom a health care provider deems antiviral therapy an appropriate treatment has access to that therapy. *Id.* As a result, the Guidance is not implicated, as it was intended to provide guidance in the extreme situation of an antiviral therapy shortage. Accordingly, Plaintiff's claims challenging the Guidance are moot and should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1).

C. Defendant Does Not Enforce the Guidance, so Injunctive Relief is Unavailable

Plaintiff seeks an order enjoining Defendant from enforcing the Guidance. An injunction may be issued issue only "in circumstances where the state official has the authority to perform the required act." *Schallop v. New York State Dep't of Law*, 20 F. Supp. 2d 384, 391 (N.D.N.Y. 1998). Plaintiff is not entitled to such an order, because the Guidance is just that—guidance. Heslin Decl., ¶ 25. It is not a mandate, and Defendant will not take any actions to enforce compliance with it. *Id.*, ¶ 26. Therefore, Plaintiff is not likely to succeed in obtaining the relief sought and his motion for a preliminary injunction should be denied.

D. The Guidance Does Not Violate the Fourteenth Amendment

To state a claim under the equal protection clause of the Fourteenth Amendment, a plaintiff must identify (1) "a law or policy that expressly classifies persons on the basis of race;" (2) "a facially neutral law or policy that has been applied in an intentionally discriminatory manner;" or (3) "a facially neutral statute or policy [that] has an adverse effect and . . . was motivated by discriminatory animus." *Brown v. City of Oneonta, New York*, 221 F. 3d 329, 337 (2d Cir. 2000). Plaintiff alleges that the Guidance violates the Fourteenth Amendment because it "discriminates on account of race in determining eligibility for COVID-19 oral antiviral

treatments” on its face. Compl., ¶ 20. However, as discussed above, the Guidance does not affect the ability of white people to receive antiviral therapies. Heslin Decl., ¶¶ 30-31. Instead, it only articulates factors that health care providers may consider when determining if a patient should be treated with antibody therapies. *Id.*, ¶ 26.

In any event, as the Second Circuit has held, a law or policy is not intentionally discriminatory when it is implemented to remedy past discrimination against a class of people. *Hayden v. County of Nassau*, 180 F. 3d 42 (2d Cir. 1999); *Jana-Rock Constr., Inc. v. N.Y. State Dep’t of Econ. Dev.*, 438 F. 3d 195, 211 (2d Cir. 2006). As it stated in *Jana-Rock*, “to equate a ‘desire to eliminate the discriminatory impact’ on some disadvantaged groups with ‘an intent to discriminate against’ other groups ‘could seriously stifle attempts to remedy discrimination.’” 438 F. 3d at 211. As a result, it is legally permissible to use “racial preferences to remedy past racial discrimination.” *Hayden*, 180 F. 3d at 50. *See also Christa McAuliffe*, 364 F. Supp. 3d at 278-279.

As the proof before the Court demonstrates, the Guidance was issued to (1) make providers and hospitals aware of the newly authorized treatments, Heslin Decl., ¶ 11, and (2) address factors to be considered when administering therapies amongst tranches of patients considering supply shortages. *Id.* The inclusion of consideration of one’s non-white race or Hispanic/Latino ethnicity in the list of considerations contained in the Guidance accounts for the disproportional impact that COVID-19 has had on members of those groups. As a result, it is not a form of unconstitutional racial discrimination, and therefore need only be supported by a rational basis. *Christa McAuliffe*, 364 F. Supp. 3d at 279-280 (policies that do not “embody a discriminatory intent” are subject to rational basis review).

The Guidance withstands rational basis review because it is rationally related to a legitimate government interest. *City of New Orleans v. Dukes*, 427 U.S. 297, 303 (1976). A policy subject to rational basis review is afforded “a strong presumption of validity,” *Heller v. Doe*, 509 U.S. 312, 319 (1993) and “must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis” for it. *F.C.C. v. Beach Communications, Inc.*, 508 U.S. 307, 313 (1993). As discussed on the face of the Guidance, and in the Declaration of Dr. Eugene Heslin, non-white and Hispanic/Latino individuals have suffered severe illness and death from COVID-19 in numbers disproportionate to those of white individuals. Heslin Decl., ¶¶ 13-22. Therefore, the consideration of non-white race and Hispanic/Latino ethnicity as a risk factor for severe disease is rationally related to the state’s interest in preventing the most severe illness and death.

Notwithstanding, even if, *arguendo*, the Guidance is found to create a classification on the basis of race, it withstands strict scrutiny. “Any preference based on racial or ethnic criteria” must be narrowly tailored to achieve a compelling state interest. *Fullilove v. Klutznick*, 448 U.S. 448, 491 (1980). The state has a compelling interest in protecting the public health, *Clementine Co. LLC v. De Blasio*, 2021 U.S. Dist. LEXIS 232058, at **39-40 (S.D.N.Y. Dec. 3, 2021), and ensuring that those most likely to face severe illness or death as a result of COVID-19 receive therapies in short supply. To accomplish this interest, the State has consulted numerous sources of medical and scientific data. Heslin Decl., ¶¶15-21. *See also Pietrangelo*, 2021 U.S. Dist. LEXIS 65632, at **2-4 (discussing the sources of scientific data relied upon in determining what groups have been disproportionately affected by COVID-19). The inclusion of non-white race as a permissive risk factor that may be considered, within the context of a comprehensive medical assessment, in the rare event that antiviral therapies are in short supply, is the narrowest way in

which the state can ensure that life-saving therapies be given to those most at risk of severed illness or death. “Narrow tailoring does not require exhaustion of every conceivable race-neutral alternative,” *Grutter v. Bollinger*, 539 U.S. 306, 339 (2003), and the issuance of the Guidance is sufficiently narrow. *Christa McAuliffe*, 364 F. Supp. 3d at 283 (“The Court can take account of the government’s ‘experience and expertise’ on its policy choices in considering whether the actions are narrowly tailored.”).

The Complaint fails to state an equal protection claim, and therefore such claim should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6). Additionally, since Plaintiff is not likely to succeed on his equal protection claim, his motion for a preliminary injunction should be denied.

E. The Guidance Does Not Violate Title VI

Title VI provides that “[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” 42 U.S.C. § 2000d. In other words, “[r]ace cannot be the basis of excluding anyone from participation in a federally funded program.” *Regents of Univ. of Cal. v. Bakke*, 438 U.S. 265, 418 (1978) (Stevens, J.).

““To state a claim for a violation of Title VI, a plaintiff must show, through specific factual allegations, that (1) the defendant discriminated on a prohibited basis; (2) the discrimination was intentional; and (3) the discrimination was a substantial or motivating factor for the defendant’s action.”” *Matthews v. New York State Dep’t of Corr. & Cnty. Supervision*, 2020 U.S. Dist. LEXIS 36226, at *48 (N.D.N.Y. Mar. 3, 2020) (quoting *Joseph v. Metropolitan Museum of Art*, 2016 U.S. Dist. LEXIS 77961, at *7 (S.D.N.Y. June 15, 2016)). *See also Burroughs v. Mitchell*, 325 F. Supp. 3d 249, 286 (N.D.N.Y. 2018). “In order to establish

intentional discrimination, Plaintiff must show that the decision maker selected or reaffirmed a particular course of action at least in part because of not merely in spite of its adverse effects upon an identifiable group.” *Burroughs*, 325 F. Supp. 3d at 286 (internal citations and quotation marks omitted).

Neither the Complaint, nor Plaintiff’s Declaration, include facts sufficient to state a claim under Title VI. First, as discussed above, the Guidance does not exclude anyone from receiving antiviral therapies on the basis of race. Instead, it merely permits health care providers to consider a patient’s non-white race or Hispanic/Latino ethnicity as a risk factor that a particular patient is likely to suffer severe illness as a result of COVID-19. The Guidance does not prevent a white patient from receiving antiviral therapies and does not automatically qualify a non-white or Hispanic/Latino patients for the therapy. Instead, whether a patient receives the therapy rests in health care providers’ medical judgment.

Second, the intent of the Guidance was not to discriminate based on race, but to advise health care providers about antiviral therapies and review/discuss with health care providers the recommended parameters, and clinical considerations, for use and eligibility for antiviral treatments. Heslin Decl., ¶ 12. Third, the Complaint does not allege that he is excluded from any “program or activity receiving Federal financial assistance.” Instead, the Complaint only alleges, in conclusory fashion, that DOH discriminates based on race in programs that receive federal funds, *see e.g.* Compl., ¶¶ 25, 29, and cites generally to descriptions of DOH agency appropriations on the Division of the Budget’s website. Pl. Mem. of Law, p. 12 (citing <https://on.ny.gov/3fsjgmY>). Plaintiff fails to articulate any facts that the antiviral therapies at issue in the Guidance are associated with any federal source of funding. Since Plaintiff fails to

allege any facts to support the essential elements of a Title VI claim, he cannot succeed on such claim and it should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

F. The Guidance Does Not Violate the ACA

“A race-discrimination claim under the ACA has the same elements as a Title VI claim.”

Prather v. Mirkil, 2020 U.S. Dist. LEXIS 64820, at *5 (D. Nev. April 14, 2020) (citing 42 U.S.C. § 18116). Therefore, for the same reasons that Plaintiff cannot succeed on his Title VI claim, Plaintiff cannot succeed on his claim under the ACA. Accordingly, Plaintiff’s motion for a preliminary injunction should be denied, and Defendant’s cross-motion to dismiss Plaintiff’s ACA claim should be granted.

POINT II

PLAINTIFF FAILS TO DEMONSTRATE IRREPARABLE HARM OR THAT THE BALANCE OF EQUITIES FAVORS AN INJUNCTION

A. Plaintiff Fails to Establish Irreparable Harm

“In the absence of a showing of irreparable harm, a motion for a preliminary injunction should be denied.” *Rodriguez by Rodriguez v. DeBuono*, 175 F. 3d 227, 234 (2d Cir. 1998) (internal quotation marks and citation omitted). The Second Circuit has emphasized that irreparable harm is “the single most important prerequisite for the issuance of a preliminary injunction.” *Id.* Plaintiff’s bare and conclusory allegations are perfunctory, and they are entirely insufficient. *Id.* at 234 (to show irreparable harm, “[t]he movant must demonstrate an injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages. . . .”). Rather than undertaking any serious effort to show irreparable harm, Plaintiff declares any such exercise to be unnecessary. In particular, Plaintiff asserts that irreparable harm is presumed upon finding a violation of his constitutional rights. Pl. Mem. of Law 13 (citing First Amendment case of *Agudath v. Israel of Am. v. Cuomo*, 983 F. 3d 620, 636 (2d

Cir. 2020)).

Plaintiff's blanket assertion, however, misreads the law in this Circuit. While some cases have permitted the presumption of harm in cases involving First Amendment and related rights, this court has acknowledged that courts "have not consistently presumed irreparable harm" even in such cases. *CompassCare v. Cuomo*, 2020 U.S. Dist. LEXIS 98930, at *30 (N.D.N.Y. Jun. 5, 2020) (quoting *Bronx Household of Faith v. Bd. of Educ.*, 331 F. 3d 342 (2d Cir. 2003)). In any event, Plaintiff does not assert a First Amendment claim, and he fails to cite any case to support the contention that irreparable harm is presumed in the equal protection and statutory claims that he does bring. *Galvin v. New York Racing Ass'n*, 70 F. Supp. 2d 163, 190 (E.D.N.Y. 1998) (while irreparable harm is presumed in First Amendment cases, "violation of due process rights, without more, is insufficient to establish irreparable harm"); *Barrett v. Harwood*, 967 F. Supp. 744, 746 (N.D.N.Y. 1997) ("the cases where courts have held that a constitutional deprivation amounts to an irreparable harm are almost entirely restricted to cases involving alleged infringements of free speech, association, privacy, or other rights as to which temporary deprivation is viewed of such qualitative importance as to be irremediable by any subsequent relief").

Additionally, irreparable harm will not be presumed where "the constitutional claim is too tenuous" and the alleged injuries too speculative, to allow such a presumption. *Carmichael v. Ige*, 470 F. Supp 3d 1133, 1150 (D. Hawaii 2020) (quoting *Goldie's Bookstore, Inc. v. Superior Court of California*, 739 F. 2d 466, 472 (9th Cir. 1984)). Plaintiff's other claim of harm—possible denial of antiviral therapies **if** he ever has COVID-19 **and** is eligible for antiviral therapies **and** there is a shortage of therapies, Pl. Mem. of Law, pp. 13-14—is entirely too speculative and tenuous to establish irreparable harm sufficient to obtain a preliminary injunction. *Jones v. Sullivan*, 2020 U.S. Dist. LEXIS 22319, at *3 (N.D.N.Y. Feb. 10, 2020) (". . . speculative, remote

or future injury is not the province of injunctive relief”).

Fatal to Plaintiff’s motion for a preliminary injunction is the lack of a shortage of antiviral therapies. Heslin Decl., ¶¶ 28-29. The only evidence before the Court establishes that antiviral therapies are available for any patient, including the Plaintiff, upon a medical determination by a health care provider. *Id.*, 30-31. The Guidance will not prevent anyone from accessing antiviral therapies based on race or ethnicity. *Id.* Therefore, Plaintiff cannot show irreparable harm.

Since Plaintiff has failed to bring forth any evidence of irreparable harm that will occur in the absence of a preliminary injunction, he fails to meet his burden and his motion should be denied.

B. The Equities and Public Interest Weigh Against a Preliminary Injunction

The balance of equities and considerations of the public interest decidedly weigh in favor of denying Plaintiffs’ request for emergency relief. “[A] plaintiff seeking a preliminary injunction must demonstrate not just that they have some likelihood of success on the merits and will suffer irreparable harm absent an injunction, but also that the ‘balance of the equities tips in [their] favor and an injunction is in the public interest.’” *Otoe-Missouria Tribe v. N.Y.S. Dep’t of Fin. Svcs.*, 769 F. 3d 105, n.4. (2d Cir. 2014) (citing *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 24 (2008)). “These factors merge when the Government is the opposing party.” *Make the Rd. N.Y. v. Cuccinelli*, 419 F. Supp. 3d 647, 665 (S.D.N.Y. 2019) (citing *Nken v. Holder*, 556 U.S. 418, 435).

Further, the court must ensure that the “public interest would not be disserved” by the issuance of a preliminary injunction. *Salinger v. Colting*, 607 F.3d 68, 80 (2d Cir. 2010). In exercising their discretion in whether to enter an injunction, courts “should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.” *N.Y.S. Rifle*

& Pistol Ass'n v. City of N.Y., 86 F. Supp. 3d 249, 258 (S.D.N.Y. 2015), *aff'd*, 883 F. 3d 45 (2d Cir. 2018) (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982)). This consideration necessarily includes the government's interest in public health. *Million Youth March, Inc. v. Safir*, 155 F. 3d 124, 125-26 (2d Cir. 1998) (modifying injunction because District Court failed to consider government's interest in, *inter alia*, public health against First Amendment rights).

The government's interests in (1) advising health care providers about antiviral therapies; and (2) reviewing and discussing with health care providers the recommended parameters for use and eligibility, and clinical considerations, for antiviral treatments are vitally important to ensure the health of New Yorkers. Accordingly, granting Plaintiff's motion for a preliminary injunction would be contrary to the public interest.

CONCLUSION

For the reasons discussed above, Plaintiff's motion for a preliminary injunction should be denied in its entirety and Defendant's cross-motion to dismiss the Complaint should be granted in its entirety with prejudice.

Dated: Albany, New York
February 18, 2022

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